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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,864	12/05/2006	Claire Mallard	129329	3442

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
10/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,864	MALLARD ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-64* is/are pending in the application.

4a) Of the above claim(s) *64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The non-final Office action mailed 17 September 2010 is hereby vacated in order to consider the preliminary amendment filed 13 November 2006 in which claims 1-32 were cancelled and claims 33-64 are presented for examination.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 33-63, drawn to an anhydrous composition and method of preparing said composition.

Group II, claim 64, drawn to a method of treating psoriasis.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The feature that is common to the two groups of inventions is the composition of claim 33, which comprises at least one active ingredient, at least one organopolysiloxane elastomer, and a thickening agent, wherein said active ingredient is in a solubilized form. US 5,654,362 discloses silicone gels which comprise the exact same organopolysiloxane elastomers as instantly claimed, and also comprise an active

ingredient and a thickening agent (octyl palmitate) (Table 1). US '362 further discloses that the compositions are useful as delivery systems for oil and water soluble substances such as vitamins (col. 7, ln. 57-58). Therefore, US '362 discloses compositions comprising an active ingredient in solubilized form, such as vitamins, an organopolysiloxane elastomer, and a thickening agent.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Active ingredients as disclosed on pages 3-7 of the instant specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 33-39 and 41-64.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

4. During a telephone conversation with Jana Meier on 12 October 2010 a provisional election was made with traverse to prosecute the invention of Group I, claims 33-63, and the specie (4E,6E)-7-[3-(3,4-bishydroxymethylbenzyloxy)phenyl]-3-ethylnona-4,6-dien-3-ol. Affirmation of this election must be made by applicant in replying to this Office action. Claim 64 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Transitional Phrase

It is noted that claims 33 and 34 recite "An anhydrous pharmaceutical composition *combining*..." The term "combining" is not a common transitional phrase, such as comprising, consisting essentially of, and consisting of. However, the examiner is construing "combining" to be synonymous with "comprising" since some of the dependent claims recite the transitional phrase "comprises" and "also comprises". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 34 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 recites "polysiloxanes (A) containing ≡Si-H groups represented by compounds of... type A^1, and compounds of... type A^2". However, compounds of type A^1 and A^2 do not comprise a triple bond to silicon. It is believed applicants intend to state that the polysiloxanes (A) contain a Si-H group.

8. Claims 34 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claim 34 recites "a low molecular weight *linear* or cyclic polysiloxane (C), being a cyclic volatile methylsiloxane chosen among hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane". However, hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane are only cyclic polysiloxanes. Therefore, it is unclear how the polysiloxane (C) can be either *linear* or cyclic when they appear to all be cyclic.

9. Claims 37, 39, 41-44, 47, 50-52, 58 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite "in particular" and "such as". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd.

App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). As one example in the present instance, claim 37 recites the broad recitation “less than or equal to 5%”, and the claim also recites “in particular less than or equal to 3%” which is the narrower statement of the range/limitation.

10. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites “vitamin D and *its derivatives*”. The broadest reasonable interpretation of derivatives of a compound covers all future improvements without regard to whether Applicants invented such improvements, which would undermine the function of the claims because it would allow Applicants to benefit from the ambiguity, rather than requiring Applicants to give proper notice of the scope of the claims to competitors. Additionally, adopting the broadest reasonable construction of the claims could retard innovation because cautious competitors may steer too far around that which Applicants actually invented, neglecting improvements that otherwise might be made. See *Halliburton Energy Services Inc. v. M-I LLC*, 85 USPQ2d 1654 (Fed. Cir. 2008).

11. Claims 60, 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 60 recites the limitation "said silicone agent" in the 4th line, and claim 62 recites the limitation “said silicon agent” in the 1st and

2nd lines. There is insufficient antecedent basis for this limitation in the claims. It is believed applicant was referring to the at least one organopolysiloxane elastomer, but the claim 60 does not recite "silicone agent" previously in the claim.

12. Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites "wherein said silicon agent is the content of elastomer is from 1% to 20%". This recitation is unclear. It is believed by the examiner that applicant intends to claim that the content of elastomer is from 1% to 20%, which would require deleting "said silicon agent is".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 63 provides for the use as claimed in claim 60, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 63 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 33-39, 42, 45-50, 52-57 and 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulz et al. (US 5,654,362).

Schulz et al. disclose preparation of a silicone powder by combining an organopolysiloxane (average structure $Me_3SiO(Me_2SiO)_{108}(MeHSiO)_{10}SiMe_3$), 1,13-tetradecadiene, octamethylcyclotetrasiloxane, platinum divinyl tetramethyl disiloxane complex catalyst (Karstedt's catalyst) followed by mechanical stirring to break the mixture into a powder (Example III). Schulz et al. then add 70 parts of this powder to 6 parts of octyl palmitate (emollient and thickening agent), 23 parts of an antiperspirant active and 1 part of fragrance (Table I). Schulz et al. disclose that the emollient can also comprise lanolin wax, and the composition is also useful as delivery systems for oil and water soluble substances such as vitamins (col. 7, ln. 27 and 57-58). Schulz et al. further disclose that other types of solvents can swell the silicone elastomer, such as alcohols and fragrances (col. 4, ln. 55 to col. 5, ln. 53). Carrying out the invention is simply a matter of combining the polysiloxane, the alpha, omega-diene, the low

molecular weight silicone oil or other solvent, and the catalyst; and mixing these ingredients at room temperature until a gel is formed (col. 5, ln. 54-59). Therefore, Schulz et al. clearly envisaged compositions comprising an active ingredient, such as oil and water soluble substances such as vitamins, and pharmaceuticals, combined with a silicone agent and a thickening agent. See also claims 1-18.

15. Claims 33-38, 42, 44-46, 54-57 and 59-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang (US 5,929,164).

Zhang discloses preparation of a silicone gel by combining an organopolysiloxane (average structure $Me_3SiO(Me_2SiO)_{93}(MeHSiO)_6SiMe_3$), 1,5-hexadiene, decamethylcyclopentasiloxane, platinum divinyl tetramethyl disiloxane complex catalyst (Karstedt's catalyst) followed by shearing and swelling with additional decamethylcyclopentasiloxane to a silicone paste containing 10.2% of the elastomer (Examples 1-5). Zhang further discloses that other types of solvents can swell the silicone elastomer, such as alcohols and fragrances (col. 6, ln. 55 to col. 7, ln. 55). Carrying out the invention is simply a matter of combining the polysiloxane, the alpha, omega-diene, the low molecular weight silicone oil or other solvent, and the catalyst; and mixing these ingredients at room temperature until a gel is formed (col. 7, ln. 56-65). Zhang discloses that silicone elastomers, gels, and pastes are capable of functioning as carriers for pharmaceuticals, biocides, herbicides, pesticides, and other biologically active substances (col. 8, ln. 64-67); as well as being useful as delivery systems for oil and water soluble substances such as vitamins (col. 8, ln. 39-40).

Therefore, Zhang clearly envisaged compositions comprising an active ingredient, such as pharmaceuticals, combined with a silicone agent and a thickening agent.

16. Claims 33, 35-47 and 53-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakuta (US 6,503,519).

Sakuta discloses dermatic cosmetic material containing a silicone composition paste comprising a cross-linked silicone polymer having hydrophilic polyoxyalkylene groups (i.e. thickener) and a silicone oil, thereby enabling stable incorporation of an antiperspirant or water-soluble vitamins and further ensuring improvements in usability (Abstract). Sakuta discloses examples of compositions comprising silicone compositions prepared by mixing $Me_3SiO(Me_2SiO)_{27}(MeHSiO)_2SiMe_3$ with ethanol, $CH_2=CHCH_2(C_2H_4O)_{10}CH_2CH=CH_2$, and a 3 wt.% ethanol solution of chloroplatinic acid, then removing the solvent; followed by 100 parts by weight of the polymer being mixed with 300 parts by weight of dimethylpolysiloxane having a viscosity of 6 mm^2/s at 25 °C (Silicone Composition No. 1), and 100 parts by weight of the polymer being mixed with 400 parts by weight of decamethylcyclopentasiloxane (Silicone Composition No. 2) (Example 1). The Silicone Composition Nos. 1 and 2 are mixed with decamethylcyclopentasiloxane, dimethylpolysiloxane, dipropylene glycol, 1,3-butylene glycol, cetyl alcohol, and vitamins C and E (Examples 10-12).

Sakuta discloses that the silicone composition paste is employed as a substrate and can be combined with lower alcohols, such as ethanol and propanol (col. 3, ln. 63 to col. 4, ln. 3) and silicone oils (col. 4, ln. 4-11). The lower alcohol is preferably present

from 100 to 1,000 parts by weight per 100 parts by weight of the silicone composition paste, the silicone oil is present from 100 to 1,000 parts by weight per 100 parts by weight of the silicone composition paste, and the vitamin is present from 0.5 to 100 parts by weight per 100 parts by weight of silicone composition paste (col. 5, ln. 13-37). Sakuta also discloses that the composition may comprise perfumes and vitamins including vitamin A, B, D, E, F, K, L, T and U (col. 5, ln. 38-43), and specifically discloses vitamins C and E present at a combined 2 or 3 wt.% (Examples 10-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 33-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulz et al. (US 5,654,362) in view of Sakuta (US 6,503,519).

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Schulz et al. are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Schulz et al. do not explicitly disclose the vitamins that can be carried by their invention to comprise vitamin D. However, one of ordinary skill in the art would readily choose vitamin D from the list of vitamins suitable for administration because it is a known vitamin and because Sakuta teaches vitamin D as suitably carried by silicone compositions for cosmetic application (col. 5, ln. 38-43).

Schulz et al. also do not explicitly disclose the amount of active agent, solvent, silicone elastomer, and agent for promoting the penetration of the active ingredient into the skin, as instantly claimed. However, one of ordinary skill in the art would readily be able to determine the necessary amounts of these components to be suitable for carrying active ingredients for topical administration.

Schulz et al. also do not explicitly disclose the use of glyceryl behenate or glyceryl dipalmitostearate in their silicone gels. However, it was well-known at the time of the instant invention that glyceryl behenate is a suitable emollient/skin conditioning agent for use in cosmetic formulations. Therefore, one of ordinary skill in the art would have been motivated to use it as an emollient in the topical formulations taught by Schulz et al.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to prepare the compositions according to Schulz et al. wherein the active agent is vitamin D, and the amounts of each component is within the scope of the instant claims. One of ordinary skill in the art at the time of the instant invention would have been able to determine the amounts of each component so that the composition acts as a suitable carrier for topical application.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

18. Claims 33-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US 5,929,164) in view of Sakuta (US 6,503,519) and Schulz et al. (US 5,654,362).

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Zhang are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Zhang does not explicitly disclose the vitamins that can be carried by the invention to comprise vitamin D. However, one of ordinary skill in the art would readily choose vitamin D from the list of vitamins suitable for administration because it is a known vitamin and because Sakuta teaches vitamin D as suitably carried by silicone compositions for cosmetic application (col. 5, ln. 38-43).

Zhang also does not explicitly disclose the amount of active agent, solvent, silicone elastomer, and agent for promoting the penetration of the active ingredient into the skin, as instantly claimed. However, one of ordinary skill in the art would readily be able to determine the necessary amounts of these components to be suitable for carrying active ingredients for topical administration.

Zhang also does not explicitly disclose incorporation of a hydrocarbon-based compound, such as hydrocarbon-based waxes (i.e., glyceryl behenate or glyceryl dipalmitostearate). However, it was well-known at the time of the instant invention that glyceryl behenate is a suitable emollient/skin conditioning agent for use in cosmetic formulations. Therefore, one of ordinary skill in the art would have been motivated to use it as an emollient in the topical formulations taught by Schulz et al.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to prepare the compositions according to Zhang wherein

the active agent is vitamin D, and the amounts of each component is within the scope of the instant claims. One of ordinary skill in the art at the time of the instant invention would have been able to determine the amounts of each component so that the composition acts as a suitable carrier for topical application.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616